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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/596,397	04/19/2007	Luc Bissonnette	056694-0010	6085

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EXAMINER

SISSON, BRADLEY L

ART UNIT	PAPER NUMBER
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1634

MAIL DATE	DELIVERY MODE
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01/09/2009

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/596,397	Applicant(s) BISSONNETTE ET AL.	
	Examiner Bradley L. Sisson	Art Unit 1634	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 12 August 2008 & 18 September 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-59 is/are pending in the application.
- 4a) Of the above claim(s) 3-15, 17-27, 30-42 and 44-59 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1, 2, 16, 28, 29 and 43 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☒ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>8/21/07, 12/18/07 & 3/12/08</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Election/Restrictions

1. Applicant's election without traverse of Group I, with the election of species as set forth in claims 16 and 43 in the reply filed on 12 August 2008 is acknowledged. Claims 1, 2, 16, 28, 29, and 43 read on the elected invention.
2. Claims 3-15, 17-27, 29-42, and 44-59 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on 12 August 2008.

Priority

3. Acknowledgment is made of applicant's claim for foreign priority based on an application filed in Canada on 13 December 2004. It is noted, however, that applicant has not filed a certified copy of the PCT/CA04/02118 application as required by 35 U.S.C. 119(b).

Specification

4. The disclosure is objected to because of the following informalities: The specification has been found to contain representations of nucleotide sequences which are not accompanied with the requisite SEQ ID NO. See, e.g., pages 27, 28, and 33.
5. Appropriate correction is required.

Claim Rejections - 35 USC § 112

6. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

7. Claims 1, 2, 16, 28, 29, and 43 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

8. For purposes of examination, the method of independent claims 1 and 28 has been construed as encompassing a hybridization assay where (a) the assay is conducted in solution; (b) the assay is conducted on the surface of a support; (c) no washing step is performed; (d) the target nucleic acid, which hybridizes to the neutral capture probe, is labeled.

9. If the probes are in solution, and the solution also comprises the nucleic acid sample and a label, seemingly there would not be any means to determine whether or not the label is associated with a probe-target complex or whether it is unincorporated, yet in solution. (Note: claims 16 and 43 require a wash step. Accordingly, claims 1, 2, 28, and 29 fairly encompass an embodiment where there is no wash step.)

10. Alternatively, if the assay were conducted on a solid support, one would not be able to distinguish between those signals that are associated with a probe-target complex and that of free label, when there is not to separate free probe, or unhybridized target, should the target be labeled (an embodiment encompassed by claims 1, 16, 28, and 43).

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Claim Rejections - 35 USC § 102

11. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

12. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

13. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

14. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later

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invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

15. Claims 1, 16, 28, and 43 are rejected under 35 U.S.C. 102(e) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over US Patent Application Publication 2003/0059817 (Okamoto et al.).

16. For purposes of examination, the expression “neutral capture probe” has been construed as encompassing probes comprising PNA, which may or may not be immobilized to a support. Support for this interpretation of the expression can be found at page 3 of the disclosure which states in part that PNA probes are neutral.

17. Okamoto et al., paragraph [0171], discloses conducting a hybridization reaction using an array of PNA capture probes and a rhodamine-labeled target nucleic acid. The method also comprises a wash step.

18. The aspect that rhodamine is used as a detectable label is considered to meet the requirement that the label have a positive charge (limitation of claim 28)

19. For the above reasons, and in the absence of convincing evidence to the contrary, claims 1, 16, 28, and 43 are rejected under 35 U.S.C. 102(e) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over US Patent Application Publication 2003/0059817 (Okamoto et al.).

20. Claims 2 and 29 are rejected under 35 U.S.C. 103(a) as being unpatentable over US Patent Application Publication 2003/0059817 (Okamoto et al.) in view of US Patent Application Publication 2003/0211527 A1 (Hartman et al.).

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21. See above for the basis of the rejection as it relates to the disclosure of Okamoto et al.

22. Okamoto et al., has not been found to disclose using a label that binds electrostatically and where the target is not labeled.

23. Hartman et al., teach a plethora of alternatives approaches to labels, and label interaction. As seen at paragraph [0079], the label may be used at any time and may be one that reacts electrostatically.

24. In view of the detailed teachings of Hartman et al., one of ordinary skill in the art at the time the invention was made would have been motivated to use labels that bind electrostatically, as such would reduce the number of steps required to produce labeled nucleic acids in a hybridization step. By incorporating this methodology into the method of Okamoto et al., said ordinary artisan would have been able to take advantage of the reproducibility, stability, and sensitivity of the PNA capture probes. In view of the well-developed state of the prior art, said ordinary artisan would have had a most reasonable expectation of success.

25. For the above reasons, and in the absence of convincing evidence to the contrary, claims 2 and 29 are rejected under 35 U.S.C. 103(a) as being unpatentable over US Patent Application Publication 2003/0059817 (Okamoto et al.) in view of US Patent Application Publication 2003/0211527 A1 (Hartman et al.).

Conclusion

26. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Bradley L. Sisson whose telephone number is (571) 272-0751.

The examiner can normally be reached on 6:30 a.m. to 5 p.m., Monday through Thursday.

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27. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ram Shukla, Ph.D. can be reached on (571) 272-0735. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

28. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Bradley L. Sisson/
Primary Examiner, Art Unit 1634